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CENTRAL FAX CENTER  
JUL 07 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re/ Application of Kenneth Iain Cumming and  
Zebunnissa Ramtoola  
Application No. 09/510,560  
Filed February 22, 2000  
Confirmation No. 3011

Examiner: J. Lundgren  
Art Unit 1639

SOLID ORAL DOSAGE FORM CONTAINING AN ENHANCER

(Attorney Docket No. P24,375-A USA)

CERTIFICATE OF MAILING

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Sheila V. Eckert

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants hereby request review of the final rejection set forth in the Office Action, mailed June 14, 2006 (the "Office Action"), in the above-referenced application. This request is being filed with a notice of appeal.

Reconsideration of the application is requested respectfully in view of the following remarks. No amendments are being filed with this request.

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## REMARKS

Claims 96 and 97 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Bachynsky et al., Irish Patent No. (11) 63119 ("Bachynsky"). According to the Examiner, Bachynsky teaches a process for providing a blend of a macromolecular drug (ceftriaxone) and a salt of a medium chain fatty acid having a carbon chain length of from 6 to 20 carbon atoms, with optional constituents Laureth 12 and Witepsol<sup>®</sup> H15. The Examiner further characterizes the blend of Bachynsky, as well as each constituent thereof, as solids at room temperature, and that the blend of Bachynsky as capable of forming an oral dosage form in which the sodium caprylate serves as an enhancer. The Examiner's characterization of Bachynsky, however, is factually erroneous and, as a result, the rejections of record are clearly not proper and are without basis.

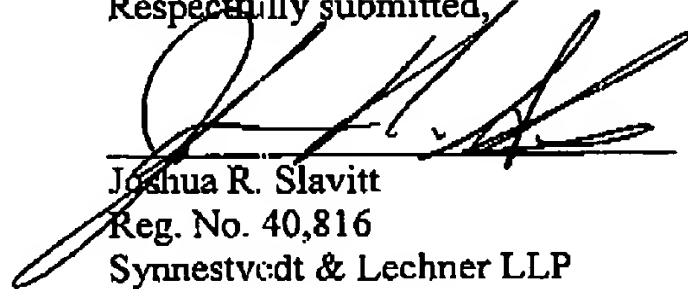
As an initial matter, it is noted that the active compound disclosed in Bachynsky which the Examiner asserts to be a macromolecule (i.e., ceftriaxone) is not actually macromolecular. The chemical formula of ceftriaxone sodium is  $C_{18}H_{16}N_8Na_2O_7S_3 \cdot 3.5 H_2O$  and has a calculated molecular weight of 661.59. By contrast, "macromolecular" is a term generally used to refer to compounds having a molecular weight in excess of 1,000. *See, e.g.,* Hackh's Chemical Dictionary at 400 (defining "macromolecular chemistry" as "the study of the preparation, properties, and uses of substances containing large and complex molecules, i.e., mol. wt. exceeding 1,000."), a copy of which is attached as Exhibit "A."

More importantly, the Examiner's characterization of Laureth 12 as a solid is factually incorrect. According to its Material Safety Data Sheet (MSDS), and contrary to the Examiner's characterization, Laureth 12 has the appearance of a "pale yellow liquid." *See* MSDS at Section 9, a copy of which is attached as Exhibit "B." Stated simply, Bachynsky does *not* disclose compositions in which each constituent is a solid at room temperature. Rather, Bachynsky's teachings are limited to compositions which comprise at least one liquid component (i.e., Laureth 12). In view of this clear limitation to the scope of its disclosure, Bachynsky does not anticipate the pending claims insofar as they require that the "blend and each of said drug, enhancer, and optional constituent(s) is a solid at room temperature." *See* Claim 96 (emphasis added). Accordingly, Bachynsky cannot serve as the basis for a rejection of the pending claims under 35 U.S.C. § 102(b).

In view of the foregoing remarks, applicants respectfully submit that the rejection set forth in the Office Action should be withdrawn. Prompt issuance of a Notice of Allowance is earnestly solicited.

Date: July 7, 2006

Respectfully submitted,



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HACKIT'S  
CHEMICAL  
DICTIONARY

Exhibit A

## M

- M.** (1) Symbol for metal. (2) Abbreviation for mega, or million. **M acid.** 1-Amino-5-naphthol-4-sulfonic acid.
- M.** Symbol for: (1) mass, (2) molel, (3) molecular weight, (4) the mathematical constant  $\log_e 10 = 0.4342944819$ . **M<sup>-1</sup>** The mathematical constant  $\log_e 10 = 2.3025850930$ . **M electron.** The electron of the *M* shell or *M* orbit, q.v. **M orbit.** The third layer or energy level, in which electrons move around the proton in the dynamic atom. **M. radiation.** A series of homogeneous X rays characteristic of the metal used as anticathode, and fainter than the *K* and *L* series. **M series.** The spectral lines produced by the *M* radiations on diffraction through a crystal grating. **Cf. Moseley spectra.** **M shell.** The third layer or energy level, in which electrons oscillate in the static atom.
- m.** Abbreviation for: (1) meter, (2) milli-, or one-thousandth part. **m<sup>2</sup>.** Abbreviation for square meter. **m<sup>3</sup>.** Abbreviation for cubic meter. **Cf. mm, mmm.**
- m.** Symbol for: (1) meta position, (2) metastable state.
- m.** Abbreviation for minim.
- μ.** Greek mu. (1) Abbreviation for: (a) micron, (b) micro-, or one-millionth of a unit. (2) Symbol for: (a) meso position, (b) magnetic permeability. **Cf. mμ, μμ.**
- Ma.** Symbol for masurium.
- ma.** Abbreviation for millimetre.
- Mao.** See also *Ma*.
- macassar oil.** Yellow fat from the seeds of *Schleichera trifida*, India and Malaya.
- mace.** Macis. The dried covering tissues of the seeds of *Myristica fragrans*; a condiment. **m. oil.** An essential oil from mace. Colorless liquid, d. 0.91; a flavoring.
- macene.**  $C_{10}H_{18} = 138.1$ . A terpene from mace oil.
- macerat.** General name for the microscope structures of the mineral constituents of coals.
- macerate.** To break up a solid by soaking in a liquid.
- Mache, Heinrich.** Austrian physicist. born, 1876.
- m. unit.** M.E. The quantity of radioactive emanation which produces a saturation current of one-thousandth of an electrostatic unit. 1 curie =  $2.8 \times 10^3$  maches. 1 mache =  $3.64 \times 10^{-10}$  curie/liter = 3.64 eman.
- machine steel.** A steel containing less than 0.3% carbon; easily machined.
- macht metal.** A forging alloy containing Cu 60, Zn 38, Fe 2%.
- Mach unit.** A unit of velocity, expressed as a percentage of the velocity of sound at sea level.
- machay bean.** The dried seeds of *Entada scandens* (Leguminosae), Queensland; a coffee substitute.
- maekelite metals.** A group of heat-resisting Ni-Cr or Ni-Cr-Fe alloys.
- Maekenzle amalgam.** An amalgam made by grinding together the solid alloys Hg-Bi and Pb-Hg.
- Mackey test.** A test of the autoxidation fire hazards of oils.
- macclayne.**  $C_{17}H_{11}O_{11} = 412.26$ . An alkaloid from *Illicium macclayana* (Sapotaceae), the tropics.
- macle.** (1) A variety of andalusite. (2) A twin crystal.
- MacLeod, John James Rickard.** 1876-1935. Scottish-Canadian biochemist, awarded Nobel Prize (with Banting) in 1923 for share in discovery of insulin.
- macleyne.** Protopine.
- maefurin.**  $C_6H_4(OH)_2CO.C_6H_4(OH)_2 = 280.1$ . Pentahydroxybenzophenone, osage orange (q.v.), moringatanic acid. Yellow crystals from the wood of *Maclura aurantiaca*, m. 200, soluble in hot water; a dye.
- macro-** Prefix (Greek μακρός = broad), indicating "large."
- macroaxis.** The long axis in orthorhombic or triclinic crystals.
- macrobacterium.** A large bacterium.
- macrocarpine.** An alkaloid from *Thalictrum macrocarpum* (Ranunculaceae). Yellow crystals, soluble in water.
- macrochemistry.** (1) The chemistry of reactions that are visible to the unaided eye. **Cf. microchemistry.** (2) Chemical operations on a large scale.
- macrotytic.** Containing rings of more than 7 C atoms.
- macrodomo.** See *dome*.
- macrolarad.** Magafarad.
- macrograph.** Photomacrograph.
- macrolide.** A substance having a macrocyclic lactone structure; as, streptomycin.
- macromolecular chemistry.** The study of the preparation, properties, and uses of substances containing large and complex molecules; i.e., mol. wt. exceeding 1,000. **Cf. polymer.**
- macroscopic.** Describing objects visible to the naked eye. **Cf. microscopic.**
- macrotn.** Cimicifugin.
- macrotoad.** The combined principles from the root of *Cimicifuga racemosa*; an antispasmodic.
- macrotyl.** Cimicifuga.
- maculanin.** Potassium amylose.
- madder.** Turkey red, q.v. **Garance.** The root of *Rubia tinctorum* species. It contains glucosides which yield, on fermentation, alizarin and purpurin; a dye and pigment in lakes.
- Maddrell salt.** A long-chain, high-molecular-weight sodium metaphosphate, made by heating sodium metaphosphate at 300; soluble in potassium salt solutions.
- mafic.** A rock-forming material, mainly magnesium and iron silicates.
- maforite.** A mineral association of kienersite and augite, q.v.

Exhibit A

# MATERIAL SAFETY DATA SHEET

**LAMBENT TECHNOLOGIES CORP.**

3938 Porett Drive  
Gurnee, IL 60031  
(800) 432-7187

**CHEMTREC EMERGENCY RESPONSE**

**TOLL FREE NUMBER:** (800) 424-9300  
**INTERNATIONAL NUMBER:** (703) 527-3887

## 1. PRODUCT IDENTIFICATION

**Product Name:** LUMULSE™ L-12  
**CTFA NAME:** Laureth-12

## 2. COMPOSITION / INFORMATION ON INGREDIENTS

	CAS Number	Weight %	ACGIH TLV	OSHA PEL
Lauryl alcohol, ethoxylated	9002-92-0		Not est.	Not est.

## 3. HAZARDS IDENTIFICATION

### Potential Health Effects

**INHALATION:** Negligible unless heated to produce vapors. Vapors or finely misted materials may irritate the mucous membranes and cause irritation, dizziness, and nausea. Remove to fresh air.

**EYE CONTACT:** May cause irritation. Irrigate eye with water for at least 15 to 20 minutes. Seek medical attention if symptoms persist.

**SKIN CONTACT:** Prolonged or repeated contact is not likely to cause significant skin irritation. Material is sometimes encountered at elevated temperatures. Thermal burns are possible.

**INGESTION:** No hazards anticipated from ingestion incidental to industrial exposure.

## 4. FIRST AID MEASURES

**EYES:** Irrigate eyes with a heavy stream of water for at least 15 to 20 minutes.

**SKIN:** Wash exposed areas of the body with soap and water.

**INHALATION:** Remove from area of exposure, seek medical attention if symptoms persist.

**INGESTION:** Give one or two glasses of water to drink. If gastro-intestinal symptoms develop, consult medical personnel. (Never give anything by mouth to an unconscious person.)

## 5. FIRE FIGHTING MEASURES

**FLASH POINT (Method Used):** > 175°C (COC)

**FLAMMABILITY LIMITS:** None known

**EXTINGUISHING MEDIA:** Dry chemical, foam, halon, CO<sub>2</sub>, water spray (fog). Water stream may splash burning liquid and spread fire.

**SPECIAL FIRE FIGHTING PROCEDURES:** Use water spray to cool drums exposed to fire.

**UNUSUAL FIRE AND EXPLOSION HAZARDS:** Firefighters should use self-contained breathing apparatus

Exhibit B

**LUMULSE L-12**

3/9/04

to avoid exposure to smoke and vapor.

**6. ACCIDENTAL RELEASE MEASURES**

**SPILL CLEAN-UP PROCEDURES:** Remove sources of ignition, contain spill to smallest area possible. Stop leak if possible. Pick up small spills with absorbent materials such as paper towels, "Oil Dry", sand or dirt. Recover large spills for salvage or disposal. Wash hard surfaces with safety solvent or detergent to remove remaining oil film. Greasy nature will result in a slippery surface.

**7. HANDLING AND STORAGE**

Store in closed containers between 50°F and 120°F. Keep away from oxidizing agents, excessive heat, and ignition sources. Store and use in well ventilated areas. Do not store or use near heat, spark, or flame; store out of sun. Do not puncture, drag, or slide this container. Drum is not a pressure vessel; never use pressure to empty.

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

**RESPIRATORY PROTECTION:** If vapors or mists are generated, wear a NIOSH approved organic vapor/mist respirator.

**PROTECTIVE CLOTHING:** Safety glasses, goggles, or face shield recommended to protect eyes from mists or splashing. PVC coated gloves recommended to prevent skin contact.

**OTHER PROTECTIVE MEASURES:** Employees must practice good personal hygiene, washing exposed areas of skin several times daily and laundering contaminated clothing before re-use.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

Boiling Point, 760mm Hg:	> 200°C
Specific Gravity, (H <sub>2</sub> O=1):	0.94
Vapor Pressure, mm Hg:	< 1
Vapor Density, (Air=1):	> 1
Volatiles, % by Volume:	< 1%
Evaporation Rate, (Butyl Acetate=1):	< 1
Solubility in Water, % by Volume:	Dispersible
Appearance and Odor:	Pale yellow liquid with a bland odor

**10. STABILITY AND REACTIVITY**

**GENERAL:** This product is stable and hazardous polymerization will not occur.

**INCOMPATIBLE MATERIALS AND CONDITIONS TO AVOID:** Strong oxidizing agents

**HAZARDOUS DECOMPOSITION PRODUCTS:** Combustion produces carbon monoxide, carbon dioxide along with thick smoke.

**11. DISPOSAL CONSIDERATIONS**

Waste may be disposed of by a licensed waste disposal company. Contaminated absorbent material may be disposed of in an approved land fill. Follow local, state and federal disposal regulations.

Exhibit B



LUMULSE L-12

3/9/04

**12. TRANSPORT INFORMATION**

UN HAZARD CLASS: N/A

**13. REGULATORY INFORMATION**

OSHA STATUS: This product is not hazardous under the criteria of the Federal OSHA hazard Communication Standard 29 CFR 1910.1200. However, thermal processing and decomposition fumes from this product may be hazardous as noted in Section 3.

TSCA STATUS: The components of this product are listed on TSCA.

**14. OTHER INFORMATION:**

NFPA Codes: Health: 1 Fire: 1 Reactivity: 0

**Revision Notes:**

3/9/04 Creation of MSDS

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process. Such information is to the best of the company's knowledge and believed accurate and reliable as of the date indicated. However, no representation, warranty or guarantee of any kind, express or implied, is made as to its accuracy, reliability or completeness and we assume no responsibility for any loss, damage or expense, direct or consequential, arising out of use. It is the user's responsibility to satisfy himself as to the suitability and completeness of such information for his own particular use.

Exhibit B